

Notice of Allowability	Application No.	Applicant(s)
	09/787,216	FRONTICELLI, CLARA
	Examiner	Art Unit
	Karen Cochrane Carlson, Ph.D.	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to election.
 2. The allowed claim(s) is/are 1-22 and 24.
 3. The drawings filed on _____ are accepted by the Examiner.
 4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) The translation of the foreign language provisional application has been received.
 6. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**
7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 8. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No. _____.
 - (b) including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).
9. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No. _____ | <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | <input type="checkbox"/> Other . |

Applicant's election with traverse of Invention I in the paper filed November 6, 2003 is acknowledged. The traversal is on the ground(s) that the instant β -globin is novel. Upon perusal of the prior art, the β -globin is novel and Inventions I and II have been rejoined.

Claims 1-24 are pending and under examination.

The β -globin mutants are set forth in 60/102,640 filed October 1, 1998. However, the α -globin mutants are not set forth until PCT/US99/22756, filed September 30, 1999. Thus, two different priority dates apply to the claim subject matter.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel A. Monaco on December 16, 2003.

Examiner's Amendments to the Claims:

In each of Claims 1 and 16, insert --- (SEQ ID NO: 3) – between “ β -globin” and “modified”.

In each of Claims 14 and 16, insert --- (SEQ ID NO: 5) – between “ α -globin” and “modified”.

Cancel Claim 23.

Claim 24 (twice amended). A mutant human α -globin polypeptide [according to claim 23, further modified by] comprising the amino acid sequence of normal human α -globin (SEQ ID NO: 5) modified by the substitution or deletion of Cys at position 104 and either the substitution of Cys for Ala at position 71[,] or the substitution of Cys for Ala at position 53.

Examiner's Amendments to the Specification:

Please add the abstract:

Abstract

Human β-globin mutant polypeptides comprise the amino acid sequence of normal human β-globin modified by (i) the substitution or deletion of Cys at amino acid positions 93 and 112, and (ii) the substitution of a Cys for a non-Cys amino acid at one other position in the polypeptide, preferable Ser at amino acid position 9. Modified human hemoglobins containing this or other β-globin mutations, and/or an α-globin mutation, are provided, as well as polymers of such modified hemoglobins. Nucleic acids, vectors, and transformed host cells for producing the β-globin mutants are provided.

This abstract is also provided on a single sheet, attached to the allowance.

The following is an **Examiner's Statement of Reasons for Allowance**: The prior art of record does not teach or suggest β-globin having Cys93 and Cys112 substituted or deleted with the additional substitution of a non-Cys amino acid with a Cys. Thus, the claimed mutant β-globin is novel. Further, the α-globin comprising Cys104 substitution and deletion with the addition of Cys at position 53 and 71 is not taught in the art. Hemoglobins and blood substitutes comprising these mutant β-globins and/or α-globins are novel over the art. The use of blood substitutes is well-known in the hemoglobin art and therefore enabled. In total, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is (703) 308-0034. The Examiner can normally be reached daily except alternate Fridays from 7:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2329. The OFFICIAL fax phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson, Ph.D.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

Abstract

Human β -globin mutant polypeptides comprise the amino acid sequence of normal human β -globin modified by (i) the substitution or deletion of Cys at amino acid positions 93 and 112, and (ii) the substitution of a Cys for a non-Cys amino acid at one other position in the polypeptide, preferable Ser at amino acid position 9. Modified human hemoglobins containing this or other β -globin mutations, and/or an α -globin mutation, are provided, as well as polymers of such modified hemoglobins. Nucleic acids, vectors, and transformed host cells for producing the β -globin mutants are provided.